REMARKS

Claims 1, 3-5, 30 and 32-36 are pending in the application, and all claims are finally rejected. In the present amendment, claim 1 is amended to recite that the protective coating is applied to the surface of the substrate in contact with the signal generating means, as disclosed in the application as-filed at page 14, lines 3-5. No new matter is introduced by this amendment.

In accordance with 37 CFR §1.116(b)(3), Applicants respectfully request entry of this amendment and consideration of the following remarks. The amendments and remarks herein could not be earlier presented because this Final Office Action is the first document Applicants have received in which the Examiner explains his view of the disclosure of Nova with respect to how the components of the Nova assay allegedly correspond to the components of the claimed assay. Applicants submit that this reasoning contains factual errors that can only now be addressed. There is therefore good and sufficient reason why this amendment is necessary and was not earlier presented. The amendment of claim 1 is a specific response to the errors in the reasoning first set forth in the Final Office Action, and it is believed to overcome all remaining rejections.

Rejection under 35 USC §102

Claims 1, 3-5, 30 and 32-36 are rejected as anticipated by Nova et al. (USP 5,741,462). It is asserted that Nova teaches a solid support (corresponding to the claimed "substrate"), a sample (corresponding to the claimed "substance"), the antibody-matrix with memory (corresponding to the claimed "signal generator") and conjugated monoclonal antibodies (corresponding to the claimed "complement") which are added to a sealed test tube (corresponding to the claimed "protective coating"). The sample bound to the antibody-matrix and sealed within the test tube is alleged to be indistinguishable from the instant claims. *See Final Office Action mailed 11/17/10; page 2, line 6 – page 3, line 2.* This proposed assignment of corresponding components between the reference and the claimed invention is in error and Applicants traverse the rejection.

In the claimed invention, the complement is fixed to a substrate for binding a corresponding substance such as a substance in a sample. The corresponding substance has signal generating means attached thereto. This defines an assay device in which, for example, an antibody is fixed to a solid surface and a labeled substance (the "corresponding substance") is bound by the fixed antibody, generating a detectable signal at the location where the complement and the corresponding substance are bound. The protective coating is applied to the surface of the substrate in contact with the signal generating means so as to perform its intended function of extending the signal generating life of the signal generating means.

To summarize the arguments set forth in more detail below:

1) Nova's antibody-matrix with memory does not correspond to the claimed signal generating means because it does not generate a signal; and

2) Nova's conjugated monoclonal antibodies do not correspond to the claimed complement because they are the only signal generating means in the Nova assay and therefore properly correspond to that feature of the claims;

When the components of the Nova device are properly construed, Nova's test tube does not anticipate the claimed protective coating because it is not applied to the surface of the substrate in contact with the signal generating means.

The antibody-matrix with memory does not correspond to the claimed "signal generating means":

In Nova, the antibody-matrix with memory uses data storage units combined with the support and programmed with information so that molecules, etc., that are in proximity or in physical contact with the matrix combination can be identified. *See Abstract; column 4, lines 46-51.* That is, the antibody-matrix with memory contains recorded identification of the antibody deposited at each site on the matrix support which can later be "read". It does not generate a signal.

The conjugated monoclonal antibodies do not correspond to the claimed "complement":

Nova's "multianalyte immunoassay," disclosed at column 29-30, is a conventional sandwich immunoassay in which "capture" antibodies specific for multiple analytes are fixed to the matrix to form the antibody-matrix with memory, and the identity of each capture antibody is recorded (see above). A sample containing antigens is reacted with the antibody-matrix with memory to capture antigens present in the sample. Monoclonal antibodies conjugated to fluorescent dyes are subsequently added to react with antigens from the sample bound to the capture antibody-matrix with memory. Fluorescence from the bound conjugated monoclonal antibody (i.e., the generated signal) is measured and quantitated. *See column 29, line 57 – column 30, line 13.*[1] The signal generated by the bound conjugated monoclonal antibodies at any particular site on the matrix indicates that an antigen corresponding to a capture antibody of the antibody-matrix with memory is present in the sample. The previously recorded identity of the corresponding capture antibody of antibody-matrix with memory is then merely "read" from the memory to identify the capture antibody and thereby identify the corresponding antigen in the sample. *See column 30, lines 56-61.*

Nova's conjugated monoclonal antibodies therefore provide the signal generation means which is missing from the antibody-matrix with memory (as discussed above). They do not correspond to the claimed "complement".

The test tube (alleged protective coating) is not in contact with the signal generating means:

Because Nova discloses a sandwich assay, the capture antibody is attached to the matrix in the antibody-matrix with memory, the antigen is bound to the capture antibody and the signal generating conjugated monoclonal antibodies are bound to the antigen. In the proposed scenario the Final Office Action requires the test tube to be both the solid support and the protective coating. The test tube is therefore necessarily

[1] It should be noted that "identity" in the context of this disclosure refers to the identity of the fluorescent label as determined by the wavelength of the emitted fluorescence, not to the identity of the antibody on the antibody-matrix with memory.

in contact with the antibody of the antibody-matrix with memory. It cannot also be (and is not) in contact with the conjugated monoclonal antibodies, which are the outermost component of the capture antibody-antigen-signal antibody sandwich.

Nova does not anticipate the claimed subject matter because it does not disclose a protective coating applied to the surface of the substrate in contact with the signal generating means. It has long been the law that a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently, in a single prior art reference. *See Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 631, 638 (Fed. Cir. 1987). Withdrawal of the rejection is therefore respectfully requested.

CONCLUSION

Applicants submit that claims 1, 3-5, 30 and 32-36 of the present patent application are now in condition for allowance, and an action passing this case to issue is respectfully requested. It is believed that no fees are due in connection with this submission, however, if fees are found to be due, the Commissioner is authorized to charge Deposit Account No. 50-3329. Please contact the undersigned by telephone if there are any issues remaining in this case.

Respectfully submitted,

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